(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 626 181 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 94100129.9

(22) Date of filing: 05.01.94

(51) Int. Cl.5: **A61N 1/362**

(30) Priority: 29.01.93 SE 9300283

(43) Date of publication of application:
30.11.94 Bulletin 94/48

(84) Designated Contracting States:
DE FR GB IT NL

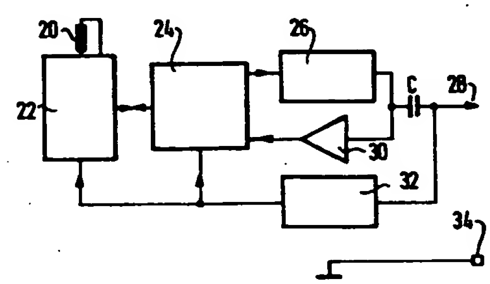
(71) Applicant: Siemens Elema AB
Röntgenvägen 2
S-171 95 Solna 1 (SE)

(72) Inventor: Högnelid, Kurt
Villavägen 306
S-137 38 Västerhaninge (SE)
Inventor: Strandberg, Hans
Landsvägen 51
S-172 36 Sundbyberg (SE)

(54) Method and device for monitoring electrodes of electrical heart stimulators.

(57) In a method for continuous, electrical monitoring of electrodes of electrical heart stimulators, comprising at least one stimulation electrode (28) and an indifferent electrode (34), the inter-electrode voltage is kept constant by regulation of a compensating current, and the magnitude of this current is measured and monitored. A device for such electrode monitoring comprises control electronics (24) and an output stage (26) for delivery to the stimulation electrode of stimulation pulses. The output stage is devised to supply the electrodes with a weak, continuous current, or repeated, pulsed current, producing a net direct current, in addition to stimulation pulses. A monitoring unit (32) is devised to sense the inter-electrode voltage and, on the basis thereof, deliver an output signal to the control electronics for the purpose of controlling said weak current so the inter-electrode voltage is kept constant at a given value, monitoring means monitoring said output signal.

FIG 2



EP 0 626 181 A1

This invention relates to a method and device for continuous, electrical monitoring of electrodes of electrical heart stimulators, comprising at least one stimulation electrode, one indifferent electrode, control electronics and an output stage for delivery of stimulation pulses to the stimulation electrode.

Damages to and other faults in the electrode system of electrical heart stimulators can develop, making reliable heart stimulation impossible. In checks on implants at clinics and hospitals, also the electrode is checked non-invasively. Also the magnitude of electrode impedance, i.e. stimulation impedance, and the conformation of pulses from surface ECG electrodes can supply information on any electrode defects in the heart stimulator.

However, previously known methods are uncertain and subjective and only reliable when "major" defects, such as electrode fracture, are present. The circumstance that the check can only be made when the patient visits a clinic or hospital is also unsatisfactory.

In EP-0 437 104 is described a method and a device for measuring electrode resistance with subthreshold pulses to defibrillation electrodes before a defibrillation shock is delivered. Here, only one current pulse with a pre-determined magnitude is emitted across the electrodes and the resulting voltage is measured and the resistance calculated.

In US-4,140,131 is described an implantable heart stimulator with two impedance detectors, i.e. a low impedance level detector and a high impedance level detector, to supply a warning if the stimulator's output impedance is outside a predetermined impedance range. Here, the detectors compare the voltage measured across a serial resistor in the electrode circuit at the delivery of stimulation pulses with pre-set limit values.

Thus, the need for electrode monitoring at implantable heart stimulators is well-known and has hitherto been accomplished in different ways, such as direct measurement on the electrode, with no stimulator connected, or by delivery of stimulation pulses, the impedance of pulses being calculated with some appropriate measurement method. The measurement value is then transmitted by telemetry, and the doctor decides whether the impedance value designates a fault-free electrode system or not.

The object of the present invention is to propose a new method and provide a new device for continuous electrical electrode monitoring at implantable electrical heart stimulators with the aid of a continuous current or repeated, pulsed current, providing a net direct current, which is so weak that it is negligible compared to the currents at e.g. pacemaker stimulation.

This object is achieved with a method and a device of the kind described in the introductory part with the characterizing features set forth in claims 1 and 3 respectively.

Thus, in the method and device a known variable, controlled current is delivered in order to maintain a given, constant electrode voltage. Here, any fault in the electrode system manifests itself as currents of highly varying magnitudes or as an inability to maintain a constant electrode voltage. An appropriate electrode voltage is of the order of magnitude of 0.5 V and an appropriate current of the order of magnitude of 50 nA. Here, it would be improper to speak of an electrode impedance, since it would, with the new measurement technique according to the invention, amount to 10 Mohm in a fault-free electrode system. It should be noted that the so-called "pulse impedance" is not the parameter measured in the method and device according to the invention. The Pulse impedance normally amounts to about 500 ohms.

The galvanic system formed by the electrode and body fluid is affected both by interruptions and short-circuits in the electrode system, and these faults will appear in the electrical quantities.

According to an advantageous additional refinement of the method according to the invention, the current to the electrodes is feedback-regulated so a constant voltage is maintained, a feedback current being measured and monitored as the compensating current. This makes possible a simple realization of the invention.

Thus, continuous electrode monitoring with a very low consumption of current is achieved with the present invention.

As exemplifications selected embodiments of the device according to the invention will now be described with reference to the attached drawings on which

FIG. 1 schematically depicts an implanted pacemaker with telemetry equipment and a monitoring device according to the invention;

FIG. 2 is a block diagram of a pacemaker equipped with a monitoring device according to the invention;

FIGS. 3 and 4 show two alternative versions of the comparator circuit in the device according to the invention;

FIG. 5 shows a version for control and monitoring of the device according to the invention,and

FIG. 6 shows an embodiment of the device according to the invention with the monitoring unit containing a potentiostat.

In FIG. 1 is schematically depicted an implanted pacemaker 2; the patient's skin is indicated at 4. The pacemaker 2 is, via an electrode cable 6, connected to a stimulation electrode 10 implanted in the heart 8. A damage to the electrode cable 6 is marked at 12, said damage being detectable with the present invention. The pacemaker 2 is

equipped with a device (not shown in this FIGURE) according to the invention for monitoring the electrode. The pacemaker 2 is further provided with telemetry equipment, indicated at 14, for communications with external telemetry equipment 16 connected to an external control and programming unit 18. Information on e.g. the condition of the electrode can be retrieved via this control and programming unit 18.

In FIG. 2 is shown a block diagram of a pacemaker which contains, in the conventional way, a telemetry coil 20 with associated electronics 22 connected to the pacemaker's control electronics 24. The control electronics 24 control an output stage 26 for supplying stimulation pulses to the stimulation electrode 28 via an output capacitor C. To the electrode 28 is also connected a heart signal detector 30 which delivers sensed heart signals to the control electronics 24 so stimulation takes place in response to detected heart signals.

The pacemaker in FIG. 2 is further equipped with a monitoring unit 32 which senses the voltage of the stimulation electrode 28 in relation to the indifferent electrode 34. The monitoring unit 32 delivers an output signal to the control electronics 24 according to the voltage measured between the electrodes 28, 34, so a current can be supplied to the electrodes to keep the voltage between them constant at a defined value between stimulation pulses. A suitable inter-electrode voltage can typically amount to about 0.5 V, and the emitted current can typically amount to about 50 nA.

A damage to the electrode system could be manifested as severe deviation in the magnitude of the current or as an inability to maintain the inter-electrode voltage at a constant value. The monitoring unit's 32 output terminal is also connected to the telemetry section 20, 22 making external electrode monitoring possible.

The current employed for the electrode monitoring is so weak that it is negligible compared to the stimulation current. Thus, electrode monitoring according to the invention causes a negligible increase in total current consumption. The current used for electrode monitoring in order to maintain the voltage between the electrodes can either be a continuous current or a repeated, pulsed current, supplying a net direct current, as noted above.

In FIG. 3 is shown a comparator 36 in the monitoring unit 32 for comparing the voltage between the electrodes 28, 34 with a predetermined reference value U_{ref}. The comparator 36 has a low-resistance output so it can be heavily loaded, and consists of an amplifier feedback-coupled through a resistor R_1. The resistance of the comparator's input is so high that the input current is negligible compared to the measurement current. On the comparator's 36 output 38 an output signal is obtained representing the "fault voltage" which, possibly via an A/D converter, is supplied to the control electronics 24 to adjust the monitoring voltage against the desired value.

The following relationship exists between the voltage U_a at the output 38, the current I and the voltage U_{ref}:

$$U_a = - I \cdot R_1 + U_{ref}$$

For $R_1 = 2$ Mohms and $I = 1$ nA, the fault voltage $U_{ref} - U_a = 2$ mV is obtained.

In FIG. 4 a modification of the circuit in FIG. 3 is shown in which the connection point between the amplifier 36 and the source of reference voltage 46 is grounded. The fault voltage then becomes

$$\Delta U = U_{ref} - U_a = I \cdot R_1$$

In this case, a fault voltage to ground U, which is directly proportional to the current I, is obtained on the amplifier's 36 output. Thus, the feedback current constitutes the measurement parameter. A fault voltage is measured and a current is supplied to correct the fault voltage.

In FIG. 5 is shown an alternative version in which the amplifier 40 is feedback-coupled via an upp/down counter 42, a D/A converter 44 and a resistor R_2. The up/down counter 42 increments if the measured voltage is less than the reference voltage U_{ref} and decrements if the measured voltage exceeds the reference voltage U_{ref} in order to induce the D/A converter 44 to deliver an analog signal representing the "fault voltage". The output signal from the D/A converter 44 is utilized for monitoring purposes and for regulating the voltage, required for electrode monitoring, between the electrodes 28, 34 towards the predetermined, constant value.

In FIG. 6 is shown an embodiment in which the monitoring unit comprises a potentiostat 48 which keeps the stimulation electrode 28 at a constant potential in relation to a third reference electrode 50, the current between the stimulation electrode 28 and the indifferent electrode 34 then being monitored.

Claims

1. A method for continuous electrical monitoring of electrodes of electrical heart stimulators, comprising at least one stimulation electrode (28) and one indifferent electrode (34), characterized in that the voltage between the electrodes (28, 34) is kept constant by regulation of a compensating current, and in that the magnitude of this current is measured and monitored.

2. A method of claim 1, characterized in that the electrodes (28, 34) are supplied with a weak, continuous current or a repeated, pulsed current, providing a net direct current, and in that the current is feedback-regulated so a constant voltage is maintained, a feedback current then being measured and monitored as the compensating current.

3. A device for continuous electrical monitoring of electrods of electrical heart stimulators, comprising at least one stimulation electrode (28), one indifferent electrode (34), control electronics (24) and an output stage (26) for delivery of stimulation pulses to the stimulation electrode, characterized in that the output stage (26) is devised to supply the electrodes (28, 34) with a weak, continuous current or repeated, pulsed current, resulting in a net direct current, in addition to stimulation pulses, and in that a monitoring unit (32) is devised to sense the inter-electrode voltage and, in accordance therewith, deliver an output signal to the control electronics to control said weak current so the inter-electrode voltage is kept constant at a defined value, monitoring means monitoring said output signal.

4. A device of claim 3, characterized in that the monitoring unit comprises a comparator (36, 40), arranged to compare the voltage between the electrodes (28, 34) with a predetermined reference value (U_{ref}), which comparator is devised as a feedback amplifier.

5. A device of claim 4, characterized in that the feedback comprises an up/down counter (42), connected in series with a D/A converter (44), said counter incrementing if the measured voltage is less than the reference value and decrementing if the measured voltage exceeds the reference value in order to control the D/A converter to deliver an analog signal as output signal from the monitoring unit (FIG. 5).

6. A device of claim 4, characterized in that the monitoring unit comprises a feedback amplifier (36) and a source of voltage (46) connected in series to a voltage (U_{ref}) which is equal to the predetermined voltage value, the amplifier's second input being connected to one electrode (28) and the second output of the voltage source being connected to the other electrode (34), so a fault voltage (U_a) proportional to the current (I) between the electrodes is obtained as output signal from the amplifier for regulatory and monitoring purposes (FIG. 3).

7. A device of claim 6, characterized in that the connection point between the amplifier and the source of voltage (46) is grounded, so a fault voltage (U) to ground which is directly proportional to the current (I) between the electrodes (28, 34) is obtained as the amplifier's output signal (Fig 4).

8. A device of claim 6 or 7, characterized in that said one electrode is the stimulation electrode (28) and said other electrode is the indifferent electrode (34).

9. A device of claim 3, characterized in that a third reference electrode (50) is provided, and in that the monitoring unit comprises a potentiostat (48) for keeping the stimulation electrode (28) at a constant potential in relation to the reference electrode, and in that the monitoring means monitor the current (I) between the stimulation electrode and the indifferent electrode (FIG. 6).

10. A device of any of claims 3 - 9, comprising telemetry equipment (20, 22) for external communications, characterized in that the output signal from the monitoring unit (32) is supplied to the telemetry equipment (20, 22) for transmission to external receiver equipment (16, 18).

FIG 1

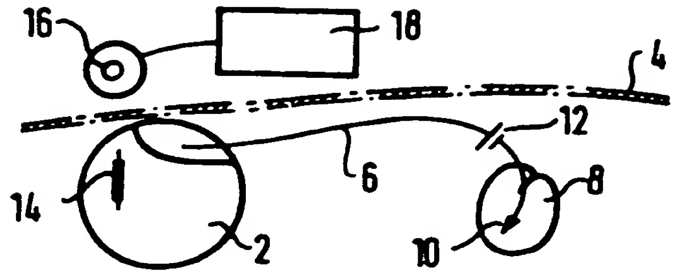


FIG 2

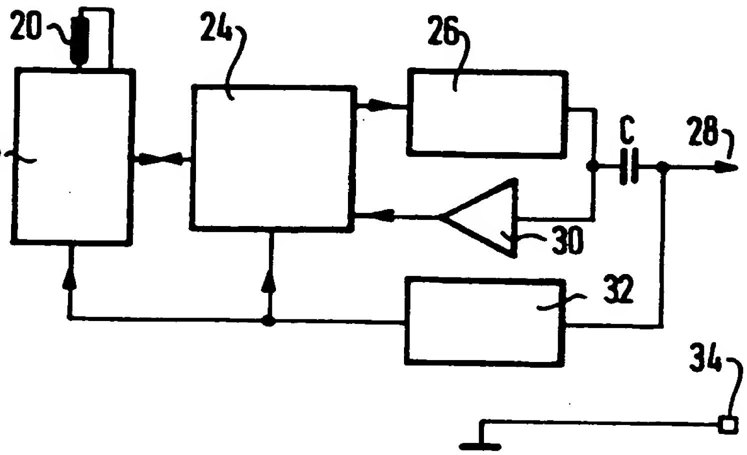


FIG 3

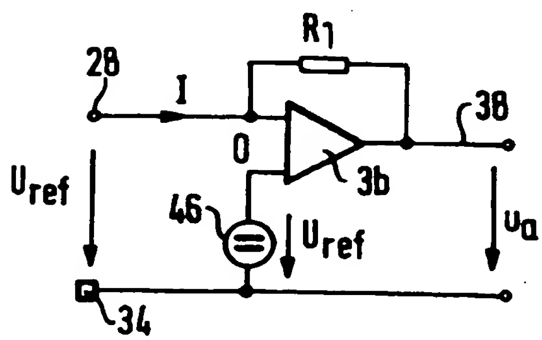


FIG 4

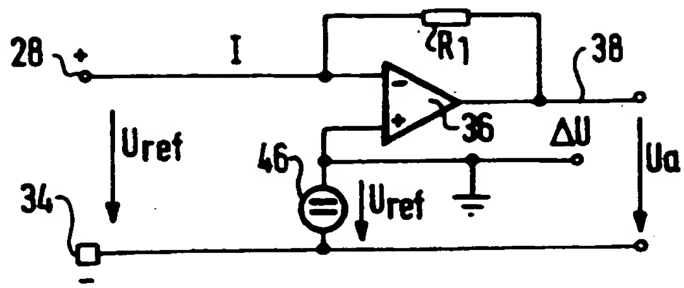


FIG 5

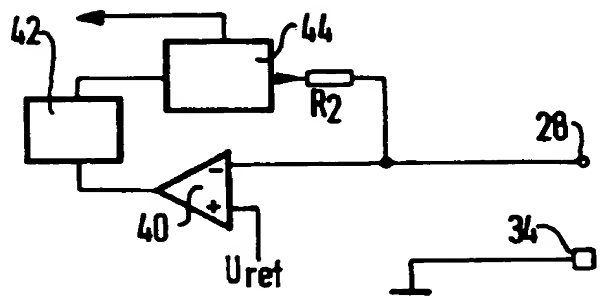
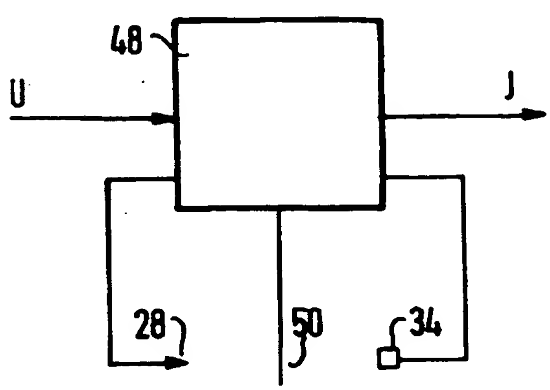


FIG 6



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EUROPEAN SEARCH REPORT

Application Number
EP 94 10 0129

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
X	US-A-4 785 812 (JAMES M. PIHL ET AL.) * column 5, line 33 - line 38; figures 1,2 * * abstract *	1	A61N1/362
A		2-10	
X	US-A-4 719 922 (ANTE L. PADJEN ET AL.) * column 4, line 63 - column 5, line 4; claim 1; figures 3A-3C *	1	
A		2-10	
A	EP-A-0 360 551 (MEDTRONIC, INC.) * abstract; figure 1 *	1-10	

TECHNICAL FIELDS SEARCHED (Int.Cl.5)

A61N

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	13 April 1994	BENGTSSON RUNE

CATEGORY OF CITED DOCUMENTS

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